

Please amend the subject application as follows:

**In the claims:**

1.-135. (Cancelled)

136. (Currently Amended) A method of diagnosing a thyroid condition in a subject which comprises:

(a) obtaining a suitable unconcentrated urine sample from the subject; and

(b) determining the concentration of thyroid stimulating hormone in the sample by a method which is not a radioimmunoassay,

wherein

(i) a concentration of thyroid stimulating hormone corresponding to greater than about 0.35  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, diagnoses hypothyroidism in the subject; and

(ii) a concentration of thyroid stimulating hormone less than about 0.04  $\mu$ IU/ml in the

subject's urine, as determined  
using the WHO reference standard  
WO 80/558, diagnoses  
hyperthyroidism in the subject.

137. (Previously Presented) The method of claim  
136, wherein step (b) further comprises:

- (1) contacting an agent capable of  
binding to thyroid stimulating  
hormone with the urine sample so as  
to bind thyroid stimulating hormone  
which is present in the sample to the  
agent;
- (2) removing unbound urine sample;
- (3) contacting the bound thyroid  
stimulating hormone with a detectable  
agent capable of binding to thyroid  
stimulating hormone so as to bind the  
detectable agent to the bound thyroid  
stimulating hormone;
- (4) removing unbound detectable agent;  
and
- (5) determining an amount of detectable  
agent which is bound to the thyroid  
stimulating hormone, thereby  
determining the concentration of

thyroid stimulating hormone in the  
urine sample.

138. (Previously Presented) The method of claim 137, wherein the agent capable of binding to thyroid stimulating hormone of step (1) is an antibody which binds to thyroid stimulating hormone.
139. (Previously Presented) The method of claim 137, wherein the agent capable of binding to thyroid stimulating hormone of step (1) is a thyroid stimulating hormone receptor.
140. (Previously Presented) The method of claim 137, wherein the detectable agent is an antibody which binds to an epitope on thyroid stimulating hormone which differs from the epitope to which the agent of step (1) binds.
141. (Previously Presented) The method of claim 137, wherein the detectable agent is labeled with a detectable marker.
142. (Currently Amended) A method of diagnosing a thyroid condition in a subject which comprises:
- (a) obtaining a suitable unconcentrated urine sample from the subject; and
  - (b) determining the concentration of thyroid stimulating hormone and the concentration of thyroxine in the

sample by a method which is not a  
radioimmunoassay,

wherein

(i) a concentration of thyroid stimulating hormone greater than about 0.35  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, and a concentration of thyroxine greater than about 1.5 ng/ml in the subject's urine diagnoses hypothyroidism in the subject; and

(ii) a concentration of thyroid stimulating hormone less than about 0.04  $\mu$ IU/ml in the subject's urine, as determined using the WHO reference standard WO 80/558, and a concentration of thyroxine less than about 0.3 ng/ml in the subject's urine diagnoses hyperthyroidism in the subject.

143. (Previously Presented) The method of claim 142, wherein step (b) further comprises:

(1) contacting an agent capable of binding to thyroid stimulating

hormone with the urine sample so as to bind thyroid stimulating hormone which is present in the sample to the agent;

- (2) removing unbound urine sample;
- (3) contacting the bound thyroid stimulating hormone with a detectable agent capable of binding to thyroid stimulating hormone so as to bind the detectable agent to the bound thyroid stimulating hormone;
- (4) removing unbound detectable agent; and
- (5) determining an amount of detectable agent which is bound to the thyroid stimulating hormone, thereby determining the concentration of thyroid stimulating hormone in the urine sample.

144. (Previously Presented) The method of claim 143, wherein the agent capable of binding to thyroid stimulating hormone of step (1) is an antibody which binds to thyroid stimulating hormone.

145. (Previously Presented) The method of claim 143, wherein the detectable agent is an antibody which binds to an epitope on thyroid

stimulating hormone which differs from the epitope to which the agent of step (1) binds.

146. (Previously Presented) The method of 143, wherein the agent capable of binding to thyroid stimulating hormone of step (1) is a receptor which binds to thyroid stimulating hormone.

147. (Previously Presented) The method of 143, wherein the detectable agent is labeled with a detectable marker.

148. (Previously Presented) The method of 142, wherein step (b) further comprises:

- (1) contacting an agent capable of binding to thyroxine with a pre-determined amount of detectable thyroxine and the urine sample, so as to form a complex between the agent and (i) the detectable thyroxine or (ii) the thyroxine present in the urine sample; and

- (2) determining an amount of detectable thyroxine which is not bound to the agent, wherein the difference between the pre-determined amount of detectable thyroxine and the amount of detectable thyroxine which is bound indicates the concentration of thyroxine present in the urine sample.

149. (Previously Presented) The method of claim 142, wherein step (b) comprises:

(1) contacting an agent capable of binding to thyroxine with a pre-determined amount of detectable thyroxine and the urine sample, so as to form a complex between the agent and (i) the detectable thyroxine or (ii) the thyroxine present in the urine sample; and

(2) determining an amount of detectable thyroxine which is not bound to the agent, thereby determining the concentration of thyroxine present in the urine sample.

150. (Previously Presented) The method of claim 148 or 149, wherein the agent of step (1) which is capable of binding to thyroxine is an antibody.

151. (Previously Presented) The method of claim 148 or 149, wherein the agent of step (1) which is capable of binding to thyroxine is a thyroxine receptor.

152. (Previously Presented) The method of claim 148 or 149, wherein the detectable thyroxine is labeled with a detectable marker.

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153. (Canceled)

154. (Canceled)

155. (Previously Presented) The method of 141 or 152, wherein the detectable marker is selected from the group consisting of a colorimetric marker, a luminescent marker, and a fluorescent marker.